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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,515	10/10/2001	Alan W Fauli	P0281494	5223

28120 7590 02/06/2004

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EXAMINER

WRIGHT, SONYA N

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 02/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/889,515

Applicant(s)

FAULL ET AL.

Examiner

Sonya Wright

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 8 and 10 is/are rejected.
- 7) ☒ Claim(s) 1-7,9 and 11 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: _____

DETAILED ACTION

This Office Action is in response to Applicants' amendment filed October 29, 2003. Claims 1-10 have been amended. Claim 11 has been added. Claims 1-11 are pending in this Office Action.

The rejection of claim 10 under 35 U.S.C. 101 has been overcome with Applicants' amendment. The rejection of claims 8 and 10 under 35 U.S.C. 112 has been maintained. The objection to claims for containing non-elected subject matter has been maintained.

Claim Objections

Claims 1-11 are objected to as containing non-elected subject matter. This objection may be overcome by limiting the claims to the elected subject matter identified for examination in the previous office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

- 1) Nature of invention.
- 2) State of prior art.
- 3) Level of ordinary skill in the art.
- 4) Level of predictability in the art
- 5) Amount of direction and guidance provided by the inventor.
- 6) Existence of working examples.
- 7) Breadth of claims.
- 8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See below:

1) Nature of the invention.

Claim 10 is drawn to a method for antagonizing an MCP-1 or RANTES mediated effect in a warm blooded animal in need of such treatment.

2) State of the prior art.

The prior arts do not indicate what diseases the instant compound can be used to treat which involve antagonizing an MCP-1 or RANTES mediated effect in a warm blooded animal.

3) Level of ordinary skill in the art.

The level of skill in the art is high. Due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to

determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Thus, the specification fails to provide sufficient support of the broad use of the compound of the claim 1 for treating all diseases pertaining to antagonizing an MCP-1 or RANTES mediated effect in a warm blooded animal.

Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001 , states that “ a patent is not a hunting license. It is not a reward for search , but compensation for its successful conclusion” and “[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable”.

4) Level of predictability in the art.

The instant claimed invention is highly unpredictable as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Hence, in the absence of a showing of treatment of all diseases related to antagonizing an MCP-1 or RANTES mediated effect in a warm blooded animal by the compound of claim 1, one of skill in the art is unable to fully predict possible results from the administration of the compound of claim 1 due to the unpredictability of the art pertaining to antagonizing an MCP-1 or RANTES mediated effect in a warm blooded animal.

The nature of pharmaceutical arts is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

5) Amount of direction and guidance provided by the inventor.

The specification provides little guidance regarding the use of the instant compound in antagonizing an MCP-1 or RANTES mediated effect in a warm blooded animal. Applicant provides background on the art of antagonizing an MCP-1 or RANTES mediated effect in a warm blooded animal on page 1. Applicant provides brief guidance on the use of the instant compound in treating diseases related to antagonizing an MCP-1 or RANTES mediated effect in a warm blooded animal on page 3, lines 16-21 and page 17, lines 12-15.

Applicant does not provide evidence that the instant compound is useful in treating diseases related to antagonizing an MCP-1 or RANTES mediated effect in a warm blooded animal. The guidance is limited because various diseases related to ion antagonizing an MCP-1 or RANTES mediated effect in a warm blooded animal have different causative agents, involve different cellular mechanisms, and, consequently, differ in treatment protocol.

6) Existence of working examples.

The specification provides limited working examples that do not support that the instant compound is useful in treating all diseases related to antagonizing an MCP-1 or RANTES mediated effect in a warm blooded animal. Applicant provides limited Examples on pages 30-39.

7) Breadth of claims.

Claim 10 is extremely broad due to the phrase "antagonizing an MCP-1 or RANTES mediated effect in a warm blooded animal". One cannot determine the metes and bounds of the claims.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not use the claimed invention without undue experimentation.

In view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test how the instant compound is useful in treating diseases related to antagonizing an MCP-1 or RANTES mediated effect in a warm blooded animal, with no assurance of success.

These rejections can be overcome by Applicant listing in claim 10 which diseases related to antagonizing an MCP-1 or RANTES mediated effect in a warm blooded animal can be treated by the instant compounds. Any diseases which are listed in claim 10 should be supported in the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 contains the phrase "such group". It is unclear what atoms or moieties are included in "such group". Correction is requested.

Response to Arguments

Applicant's arguments filed 10-29-03 have been fully considered. Regarding the restriction requirement, Applicant argues that the situation presented in Example 18 of the Administrative Instructions under the PCT, Annex B, Example 18, is very similar to the present case. Applicant argues that the claimed compounds include an indolyl moiety as "the significant structural element which is shared by all of the alternatives" and are alleged to possess the same utility. Applicant further argues that accordingly, unity of invention is present in the current claims.

However, the claims herein lack unity of invention under PCT Rule 13.1 and 13.2 since the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art. The compounds claimed contain an indole core containing variables R1, R2, R3, R4, R5, R6, R7, R8, R9, X, etc. . . The compounds defined in the claims lack a significant structural element because the indole core is known (see the attached reference: Organic Chemistry, 5th Edition, Fessenden and Fessenden, 1994, page 790, Table

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19.1). The substituents on the ring vary and when taken as a whole result in vastly different compounds. Accordingly, unity of invention is considered to be lacking a restriction of the invention in accordance with the rules of unity of invention is considered to be proper. Additionally, the vastness of the claimed subject matter and the complications in understanding the claimed subject matter imposes a burden on any examination of the claimed subject matter.

Regarding the rejection under 35 U.S.C. 101, Applicant argues that Applicants have amended claim 10 to recited steps involved in the method. However, claim 10 has been amended to recite a mechanism instead of a method of use, see the rejection under 35 U.S.C. 112 *supra*.

Regarding the rejection under 35 U.S.C. 112, Applicant argues that a person skilled in the art would be able to, at the very least refer to common textbooks such as those by Morrison and Byrd or March to determine specific reaction conditions with no more than routine experimentation. Applicant further argues that the specification provides ample guidance to enable a skilled artisan to practice the invention without undue experimentation. Applicants' arguments have been persuasive with regard to the phrase "reacting a compound of formula (VII) with a compound of formula (VIII)". However, claim 8 is rendered indefinite due to the phrase "such groups". It is unclear what atoms or moieties are included in "such groups". See the rejection under 35 U.S.C. 112 *supra*.

Regarding the rejection of claim 10 under 35 U.S.C. 112, Applicant argues that the amendment to claim 10 to recite steps involved in the method renders the

Examiner's rejection moot. However, claim 10 has been amended to recite a mechanism without an intended use. See the rejections under 35 U.S.C. 112 supra.

The abstract submitted by Applicant has been entered in the file.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (703) 308-4539. The examiner can normally be reached on Monday-Friday from 8:00 AM - 5:30 PM.

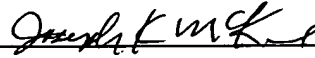
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial

fax phone number for this Group is (703) 308-7922. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1235.

A handwritten signature in cursive script, appearing to read "Joseph K. McKane", is written over a horizontal line.

Joseph K. McKane

Supervisory Patent Examiner

Group 1600

Sonya Wright

January 22, 2004